



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2019-D-0661]

Modifications to Compliance Policy for Certain Deemed Tobacco Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled "Modifications to Compliance Policy for Certain Deemed Tobacco Products." The draft guidance discusses changes to the compliance policies for premarket review requirements for certain deemed tobacco products and describes how FDA intends to prioritize its enforcement resources with regard to the marketing of certain deemed tobacco products that do not have premarket authorization.

DATES: Submit either electronic or written comments on the draft guidance by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including

attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.

- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2019-D-0661 for "Modifications to Compliance Policy for Certain Deemed Tobacco Products." Received comments will be placed in the docket and, except for those submitted as "Confidential

Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the

prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for single copies of this draft guidance to the Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request or include a fax number to which the draft guidance may be sent. See the SUPPLEMENTARY INFORMATION section for information on electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Gerie Voss, Center for Tobacco Products, Food and Drug Administration, Document Control Center, 10903 New Hampshire Ave., Bldg. 71, Rm. G335, Silver Spring, MD 20993-0002, email: CTPRegulations@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled "Modifications to Compliance Policy for Certain Deemed Tobacco Products."

The Family Smoking Prevention and Tobacco Control Act (Pub. L. 111-31) (Tobacco Control Act) granted FDA the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect public health generally and to reduce tobacco use by minors. The Tobacco Control Act also gave FDA the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

In accordance with that authority, on May 10, 2016, FDA issued a final rule entitled "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (the final deeming rule) deeming all products that meet the statutory definition of a tobacco product, except accessories of deemed tobacco products, to be subject to FDA's tobacco product authority. This included electronic nicotine delivery systems (ENDS), cigars, waterpipe (hookah) tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976, May 10, 2016).

Among other requirements, these statutory provisions and implementing regulations prohibit sales of tobacco products to minors and impose certain premarket-review requirements for new tobacco products—i.e., those that were not commercially marketed in the United States as of February 15, 2007. In addition, the preamble to the final deeming rule explained that, for deemed tobacco products on the market as of August 8, 2016, FDA did not intend to initiate enforcement for failure to have premarket authorization during two compliance periods: one for submission and FDA receipt of applications and one for obtaining premarket authorization (81 FR 28974 at 29011).

In May 2017, FDA published a guidance document entitled "Three-Month Extension of Certain Tobacco Product Compliance Deadlines Related to the Final Deeming Rule" under which the Agency, as a matter of enforcement discretion, stated its intention not to begin enforcement for an additional 3 months for all future compliance dates for requirements under the final deeming rule. In July 2017, FDA announced a new comprehensive plan for tobacco and

nicotine regulation that would serve as a multiyear roadmap. In an effort to strike an appropriate balance between regulation and encouraging development of innovative tobacco products that may be less dangerous than cigarettes, the Agency announced that it would be providing targeted relief on some timelines described in the preamble to the final deeming rule. In accordance with this comprehensive plan announcement, in August 2017, FDA stated its intention to further extend the period during which it would not initiate enforcement action for requirements under the final deeming rule ("August 2017 Compliance Policy").

Recent data has documented a significant increase in youth use of ENDS products. Data from the 2018 National Youth Tobacco Survey, as described in the guidance, reveals the magnitude in the increase of youth use of ENDS products. In addition, evidence from the 2016-2017 (Wave 4) Population Assessment of Tobacco and Health (PATH) Study and other studies, as described in the guidance, indicates that minors are attracted to flavored ENDS products. In light of this public health threat, FDA has reconsidered and, in its discretion, plans to modify the August 2017 Compliance Policy as to the premarket authorization requirements for certain flavored ENDS products that were on the market on August 8, 2016, and to replace it with a new policy as described in the draft guidance.

The draft guidance is intended to discuss how FDA plans to prioritize its enforcement resources with regard to certain deemed tobacco products in the United States that do not have the required FDA premarket authorization for marketing. Goals of the guidance are to encourage more prompt filing of premarket submissions for certain ENDS products, to focus the Agency's enforcement resources where there is a greater threat to public health, and to balance that public health threat against the potential benefit to providing adult smokers noncombustible options to allow them to completely switch from the use of combustible products.

II. Significance of Draft Guidance

FDA is issuing this draft guidance consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the compliance policy for certain deemed tobacco products. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. This guidance is not subject to Executive Order 12866.

III. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520). The collections of information in 21 CFR 1107.1(b) and (c) have been approved under 0910-0684; the collections of information under section 910 of the FD&C Act (21 U.S.C. 387j) have been approved under OMB control number 0910-0768. The collections of information in section 905(j) of the FD&C Act (21 U.S.C. 387e(j)) have been approved under OMB control number 0910-0673.

IV. Electronic Access

Persons with access to the internet may obtain an electronic version of the draft guidance at either <https://www.regulations.gov> or <https://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm>.

Dated: March 11, 2019.

Scott Gottlieb,

Commissioner of Food and Drugs.

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